Remarks

Claims 1-10 were pending in the subject application. The undersigned avers that no new matter is introduced by this amendment. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-10 are currently before the Examiner for his consideration. Favorable consideration of the pending claims is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion. These amendments should not be construed as an indication of Applicants' agreement with or acquiescence to, the rejections of record. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

The specification has been amended to correct grammatical informalities and to include references to the new figures. The paragraph at page 2, lines 18-27 has been amended to replace the phrase "pressure applied from proximal towards distal" with "pressure applied from the proximal end towards the distal end" and to replace the phrase "it can be imaged due its susceptibility artifact" with "it can be imaged due to its susceptibility artifact". The paragraph at page 2, lines 35-38 has been amended to replace the phrase "pressure from proximal to distal" with "pressure from the proximal end to the distal end." The paragraph at page 3, lines 1-4 has been amended to replace the phrase "It could be a gluing, or the main part 4 is pinched over or under the distal front part 2 at the connection 3" with "It could be glued as shown in Figures 2A and 2B, or the main part 4 can be pinched over or under the distal front part 2 at the connection 3". No new matter is introduced by this amendment.

The specification has been objected to as failing to provide proper antecedent basis for the claimed subject matter. The Office Action at page 2 states that the "specification fails to provide antecedent basis for the metallic distal part comprising nickel-titanium (claim 1) or stainless steel (claim 8); the main part and the distal part being connected by shrinkdown plastic tubing (claim 6); a core in the center of the main part (claim 7); or the artificial material being polypropylene, polyethylene, polyetherimides, and polyetheretherketone (claim 9)." Accordingly, the specification

has been amended. The paragraph at page 2, lines 29-33, has been amended to add "Metallic distal part 2 can comprise nickel-titanium or a stainless steel alloy, for example". The paragraph at page 2, lines 35-38, has been amended to add "The artificial material can be, for example, polypropylene (PP), polyethylene (PE), polyetherimides (PEI), or polyetheretherketone (PEEK)", "In one embodiment, as shown in Figure 5, MRI-inert plastics main part 4 has a core in the center of main part 4", and " In an embodiment, the core can comprise an insulant material". The paragraph at page 3, lines 1-4, has been amended to add "In another embodiment, as shown in Figure 4, main part 4 and distal part 2 are connected by shrink-down plastic tubing." Therefore, the corrected specification provides antecedent basis for all the claimed elements. No new matter is added by the amendments. The Examiner's acceptance of these corrections is respectfully requested.

The drawings have been objected to under 37 CFR 1.83(a). New drawing sheets are hereby provided in accordance with 37 CFR 1.121(d), illustrating the following claim elements in alternative embodiments: the distal part and main part being glued together; the distal part being pinched onto the main part; the distal part being connected by shrinkdown plastic tubing; and a core in the center of the main part. Because these features are fully described by the written specification, no new matter has been added. The Examiner's acceptance of these drawing changes is respectfully requested.

Claims 1, 3, and 9 have been rejected under 35 USC §102(b) as anticipated by Gambale *et al.* (U.S. Patent No. 4,922,924). Applicants respectfully traverse this rejection.

The Office Action, at page 3 paragraph 4, states that "Gambale *et al.* discloses an MRI compatible device for guiding catheters having a metallic wire distal part (24; col. 2, lines 60-61) and an MRI-inert plastics main part (col. 2, line 66 – col. 3, line 4). The main part comprises an artificial material selected from the group of polypropylene, polyethylene, polyetherimides, and polyetheretherketone (col. 2, line 66 - col. 3, line 4)."

However, the Gambale *et al.* reference does not disclose a metallic wire distal part and an MRI-inert plastics main part as claimed in claim 1. Rather, the Gambale *et al.* reference teaches, at col. 1, lines 47-68,

> "[a] guidewire, in accordance with the invention, has an elongate flexible shaft having a tapered distal portion. A helical coil formed from a radiopaque metal

is mounted on the distal end of the shaft over the tapered portion, the tapered portion being received in and extending through the coil. The coil is formed from two elements, including a first coil formed from a highly radiopaque metal and a second, shorter coil that is formed from a flexible non-radiopague polymeric material. The polymeric, plastic, non-radiopaque portion is wound together with the proximal end of the radiopaque coil so as to define a bifiler proximal coil segment characterized by alternating highly readipaque and non-radiopaque coils. The portion of the coil that extends beyond the distal end of the plastic coil is entirely highly radiopaque and presents a darker image on the fluoroscope. Thus the guidewire provides a distal coil having a highly radiopaque distal segment and a moderately radiopaque proximal segment which will not completely obstruct visualization of arteries into which radiopaque contrast liquid has been injected." (underline added for emphasis).

In addition, the Gambale *et al.* reference, at col. 2, line 58 – col. 3, line 4, teaches "the coil assembly is formed from a first coil 24 which extends the full length of the coil assembly formed from a highly radiopaque material such as a platinum tungsten alloy . . . [a] shorter helical coil 30 formed from a non-radiopaque material, such as an appropriate flexible plastic, polymeric material (for example, polypropylene) is interposed among the coils of the first coil 24 along a proximal portion of the first coil 24 in a bifilar arrangement in which the turns of the first and second coils 24, 30 alternate" (underline added for emphasis). The shorter helical coil 30 of the Gambale *et al.* reference is not an MRI-inert plastics main part as claimed in claim 1 of the subject application. Instead the shorter helical coil of the Gambale *et al.* reference "is wound together with the proximal end of the radiopaque coil so as to define a **bifiler proximal coil segment** characterized by alternating highly readipaque and non-radiopaque coils". Accordingly, the Gambale *et al.* reference does not teach an MRI compatible device for guiding catheters inside human or animal vessels, comprising a metallic wire distal part and an MRI-inert plastics main part as claimed in claim 1, 3, and 9.

Claims 1, 3, 4, 7, 9, and 10 have been rejected under 35 USC §102(b) as anticipated by Johanson *et al.* (U.S. Patent No. 5,596,996). Applicants respectfully traverse this rejection.

The Office Action, at page 3 paragraph 6, states that "Johanson *et al.* discloses an MRI compatible device for guiding catheters having a metallic wire distal part (45) and an MRI-inert plastics main part (col. 4, line 3-42). The distal part and the main part are glued together (col. 5, line 24). The main part comprises a core comprising an insulant material (col. 4, lines 37-42). The main part comprises an artificial material selected from the group of polypropylene, polyethylene, polyetherimides, and polyetheretherketone (col. 4, lines 37-42)."

However, the Johanson *et al.* reference does not disclose an MRI compatible device for guiding catheters inside human or animal vessels, comprising a metallic wire distal part and an MRI-inert plastics main part as claimed in claim 1. Rather, the Johanson *et al.* reference teaches, at col. 4, lines 3-4, "tube **30** is supported by a distally tapering core wire **25** . . . [t]he core wire **25** can be constructed of stainless steel" (underline added for emphasis). The long stainless steel core wire of the Johanson *et al.* reference would cause artifacts in an MR image and does not suggest use in an MRI system. Furthermore, a stainless steel core wire is not an inert plastics main part. In addition, the Johanson *et al.* reference, at col. 3, lines 17-31, discloses "[p]rior art guidewires are currently constructed with a spring coil over the tapered distal end of the core wire . . . [i]nstead of a spring coil, however, applicant's guidewire **20** is constructed using a tube **30** which can be made of an elastomer or an alloy which is highly flexible without permanent deformation such as a shape memory alloy . . . [a] preferred embodiment uses NiTi 49-51 atom % Ni" (underline added for emphasis). For the preferred embodiment, the tube of the Johanson *et al.* reference is not an MRI-inert plastics main part, nor is it a metallic wire distal part.

The Johanson *et al.* reference does not teach a metallic wire distal part as claimed in claim 1 of the subject application. Rather, the Johanson *et al.* reference, at col. 5, lines 21-26, teaches "radiopaque marker band **45** can be placed in the distal inner lumen of the tube **30** approximately 1-2 cm from the tip **40** enabling the physician to visualize the progress of the tip **40** under fluoroscopy . . . [t]he marker band **45** can be attached by heat bonding or with an adhesive such as epoxy." Instead of a metallic wire distal part, marker band **45** is a radiopaque band. The marker band **45** of the Johanson *et al.* reference is designed for x-ray imaging, not MRI.

Accordingly, the Johanson *et al.* reference does not teach an MRI compatible device for guiding catheters inside human or animal vessels, comprising a metallic wire distal part and an MRI-inert plastics main part as claimed in claim 1, 3, 4, 7, 9, and 10.

Claims 1-5 and 7-10 have been rejected under 35 USC §102(b) as anticipated by Muni *et al.* (U.S. Patent No. 6,375,629). Applicants respectfully traverse this rejection.

The Office Action, at page 5 paragraph 8, states that "Muni *et al.* discloses an MRI compatible device for guiding catheters having a metallic wire distal part (26) comprising nickel titanium or stainless steel (col. 5, lines 8-10), and an MRI-inert plastics main part (12; col. 4, lines 29-30). The distal part is pinched with the main part (col. 5, lines 45-47). The main part comprises a core comprising an insulant material (12; col. 4, lines 29-30). The main part comprises and artificial material selected from the group of polypropylene, polyethylene, polyetherimides, and polyetheretherketone (12; col. 4, lines 29-30). Additionally, Muni *et al.* discloses a metallic wire distal part (32) glued to the main part (col. 5, lines 27-30)."

However, the Muni *et al.* reference does not teach or suggest an MRI compatible device for guiding catheters inside human or animal vessels, comprising a metallic wire distal part and an MRI-inert plastics main part, as claimed in amended claim 1.

Rather, the Muni *et al.* reference, at col. 5, lines 23-36, teaches "[a]s shown in FIG. 2, coil **32** is provided around the core wire **26** . . . [c]oil **32** is formed of a suitable radiopaque material such as gold, platinum, or a platinum alloy" (underline added for emphasis). The radiopaque material teaches or suggests use in an x-ray system, not an MRI system. The coil **32** taught by the Muni *et al.* reference is not MRI compatible. Therefore the Muni *et al.* reference does not teach or suggest an MRI compatible device for guiding catheters inside human or animal vessels, comprising a metallic wire distal part and an MRI-inert plastics main part, as claimed in amended claim 1

Accordingly, reconsideration and withdrawal of the rejections of claims 1-5 and 7-10 under 35 USC §102(b) is respectfully requested.

Claim 6 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Muni *et al.* (U.S. Patent No. 6,375,629) as applied to claim 1 above and further in view of Ryan *et al.* (U.S. Patent No. 5,492,532). The applicants respectfully traverse this grounds for rejection. The deficiencies of the Muni *et al.* reference have been discussed above with respect to the rejection of

claim 1, from which claim 6 depends. The Ryan *et al.* reference does not cure such defects. The Muni *et al.* and Ryan *et al.* references, alone or in combination, do not teach or suggest the subject invention as claimed in claim 6. Accordingly, applicants assert a *prima facie* case of obviousness has not been presented with respect to claim 6. Therefore, reconsideration and withdrawal of the rejection of claim 6 under 35 U.S.C. §103(a) is respectfully requested.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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Attachments